IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ARBUTUS BIOPHARMA CORPORATION and GENEVANT SCIENCES GmbH, Plaintiffs, v. MODERNA, INC. and MODERNATX, INC., Defendants.	C.A. No. 22-252-JDW [redacted]
MODERNA, INC. and MODERNATX, INC., Counterclaim-Plaintiffs, v. ARBUTUS BIOPHARMA CORPORATION and GENEVANT SCIENCES GmbH, Counterclaim-Defendants.	[redacted] REDACTED - PUBLIC VERSION

MODERNA'S STATEMENT OF UNDISPUTED FACTS IN SUPPORT OF ITS MOTION FOR SUMMARY JUDGMENT

Pursuant to Rule 56 of the Federal Rules of Civil Procedure, the Court's Policies and Procedures for Civil Matters, Section 11, and the Court's Scheduling Order (D.I. 485), Moderna, Inc. and ModernaTX, Inc. (collectively, "Moderna") submits the following Statement of Undisputed Facts in support of its motion for summary judgment.

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TABLE OF ABBREVIATIONS

Abbreviation	Full Description
"Moderna"	Collectively, Moderna, Inc. and ModernaTX, Inc.
"Genevant"	Genevant Sciences GmbH
"Arbutus"	Arbutus Biopharma Corp.
"Plaintiffs"	Collectively, Arbutus and Genevant
"the '069 patent"	U.S. Patent No. 8,058,069 (Ex. 2)
"the '668 patent"	U.S. Patent No. 8,822,668 (Ex. 3)
"the '651 patent"	U.S. Patent No. 9,504,651 (Ex. 4)
"the '359 patent"	U.S. Patent No. 8,492,359 (Ex. 5)
"the '435 patent"	U.S. Patent No. 9,364,435 (Ex. 6)
"the '378 patent"	U.S. Patent No. 11,141,378 (Ex. 7)
"Ratio Patents"	Collectively, the '069 patent, the '359 patent, the '668 patent, the '435 patent and the '378 patent.
"C-34"	Contract No. 75A50120C00034 (Ex. 9)
"C-100"	Contract No. W911QY20C0100 (Ex. 1)
"MacLachlan"	U.S. Patent App. Pub. No. 2006/0008910 (Ex. 57)
"mol % range limitations"	Collectively, the cationic, non-cationic, conjugated lipid claim limitations recited in the Ratio Patents
"DOE"	doctrine of equivalents
"PTO"	U.S. Patent and Trademark Office
"'069 IPR"	*Moderna Therapeutics, Inc. v. Arbutus Biopharma Corp.*, IPR2019-00554 (P.T.A.B.).
"'435 IPR"	*Moderna Therapeutics, Inc. v. Protiva Biotherapeutics, Inc.*, IPR2018-00739 (P.T.A.B.).
"'069 Appeal"	*Moderna TX, Inc. v. Arbutus Biopharma Corp.*, No. 2020-2329 (Fed. Cir.).
"'435 Appeal"	*Moderna TX, Inc. v. Protiva Biotherapeutics, Inc.*, No. 2020-1184, -1186 (Fed. Cir.).
"LNP"	lipid nanoparticle

Abbreviation	Full Description
"Blenke"	Blenke et al., *Critical evaluation of quantification methods for oligonucleotides formulated in lipid nanoparticles*, 548 International J. Pharms. 793–802 (2018) (Ex. 60)

TABLE OF EXHIBITS[1]

Ex. No.	Description
1.	W911QY20C0100 Contract (MRNA-GEN-00079284 through MRNA-GEN-00079336)
2.	U.S. Patent No. 8,058,069 to Yaworski et al.
3.	U.S. Patent No. 8,822,668 to Yaworski et al.
4.	U.S. Patent No. 9,504,651 to MacLachlan et al.
5.	U.S. Patent No. 8,492,359 to Yaworski et al.
6.	U.S. Patent No. 9,364,435 to Yaworski et al.
7.	U.S. Patent No. 11,141,378 to Yaworski et al.
8.	White House Proclamation (MRNA-GEN-02657322 through MRNA-GEN-02657325)
9.	75A50120C00034 Contract (MRNA-GEN-02079767 through MRNA-GEN-02079878)
10.	White House Proclamation (MRNA-GEN-02696526 through MRNA-GEN-02696535)
11.	HHS Covid-19 Vaccine Strategy (MRNA-GEN-02676917 through MRNA-GEN-02676927)
12.	HHS Explaining Operation Warp Speed (MRNA-GEN-02676415 through MRNA-GEN-02676419)
13.	Aug 11, 2020 DoD Press Release (MRNA-GEN-02670803 through MRNA-GEN-02670805)
14.	June 3, 2025 Letter from F. Elenberg to M. McLennan
15.	May 20, 2024 Deposition Transcript of Hamilton Bennett
16.	W911QY20C0081 Solicitation, Offer and Award (MRNA-GEN-00904611 through MRNA-GEN-00904630)
17.	Barda Technical Evaluation (DOD_000003510 through DOD_000003521)
18.	P00003 Amendment of C-100 (MRNA-GEN-00079170 through MRNA-GEN-00079200)
19.	P00004 Amendment of C-100 (MRNA-GEN-00079068 through MRNA-GEN-00079097)
20.	P00007 Amendment of C-100 (MRNA-GEN-00079201 through MRNA-GEN-00079231)

[1] All cited exhibits are attached to the accompanying Declaration of Mark. C. McLennan.

Ex. No.	Description
21.	P00031 Amendment of C-100 (MRNA-GEN-00457581 through MRNA-GEN-00457583
22.	July 25, 2025 Declaration of Albert Thomas in Support of Moderna's Motion for Summary Judgment Under 28 U.S.C. § 1498(a)
23.	Dec 18 2020 FDA EUA Letter (MRNA-GEN-02463357 through MRNA-GEN-02463365)
24.	BARDA Web Announcement (MRNA-GEN-02677440 through MRNA-GEN-02677442)
25.	May 23, 2024 Deposition Transcript of Albert Thomas
26.	August 27, 2024 Deposition Transcript of Jean Santoli
27.	September 10, 2024 Deposition Transcript of Robert Johnson
28.	C-100 Contract Sales Spreadsheet (MRNA-GEN-00467749)
29.	November 25, 2024 Expert Report of Catharine M. Lawton
30.	May 13, 2025 Declaration of George Rutherford
31.	May 20, 2025 Declaration of Christopher Vellturo
32.	Jan 15, 2021 White House Fact Sheet (MRNA-GEN-02673093 through MRNA-GEN-02673098)
33.	December 8, 2020 Remarks by President Trump at the Operation Warp Speed Vaccine Summit (Exhibit 3 of Alex Brill Deposition)
34.	Dec 2021 ASPE Research Report (MRNA-GEN-02657270 through MRNA-GEN-02657309)
35.	ARDA Memo re Purchase of Moderna Vaccine (HHS-0000414 through HHS-0000416)
36.	COVAX Data Brief (MRNA-GEN-02669317)
37.	Sept 20, 2021 Moderna US Monitoring Report (MRNA-GEN-02119128 through MRNA-GEN-02119188)
38.	Natl Strategy for Covid-19 Response (MRNA-GEN-02670578 through MRNA-GEN-02670777)
39.	June 3, 2021 White House Statement (GENV-01086629 through GENV-01086630)
40.	Covid-19 Dose Tracking Template (MRNA-GEN-00459217)
41.	February 8, 2024 Markman Transcript
42.	November 25, 2024 Opening Expert Report of Dr. Michael Mitchell
43.	Plaintiffs' February 8, 2024 Claim Construction Hearing Demonstratives

Ex. No.	Description
44.	Plaintiff Genevant Sciences GMBH's Second Supplemental Responses and Objections to Defendants Moderna, Inc. and ModernaTX, Inc's Second Set of Interrogatories (Nos. 8-10)
45.	Plaintiff Arbutus Biopharma Corporation's Second Supplemental Responses and Objections to Defendants Moderna, Inc. and ModernaTX, Inc's Second Set of Interrogatories (Nos. 8-10)
46.	March 21, 2025 Reply Expert Report of Dr. Michael Mitchell
47.	May 29, 2024 Deposition Transcript of Ian MacLachlan
48.	April 26, 2024 Deposition Transcript of Lloyd Jeffs
49.	May 3, 2024 Deposition Transcript of Adam Judge
50.	May 28, 2024 Deposition Transcript of Stephen Reid
51.	May 23, 2024 Deposition Transcript of Sunny Jeng
52.	February 26, 2019 Deposition Transcript of James Heyes, No. IPR2018-00680, Ex. 1026
53.	April 11, 2024 Deposition Transcript of George Schuster
54.	November 14, 2023 Deposition Transcript of David Thompson
55.	February 14, 2025 Responsive Expert Report of Dr. Niren Murthy Regarding Validity
56.	April 16, 2024 Deposition Transcript of Robert Prud'Homme
57.	U.S. Patent App. Pub. No. 2006/0008910 to MacLachlan
58.	April 9, 2024 Deposition Transcript of Pierre Meulien
59.	April 22, 2024 Deposition Transcript of Niren Murthy
60.	Blenke et al., Critical evaluation of quantification methods for oligonucleotides formulated in lipid nanoparticles, 548 International J. Pharms. 793–802 (2018) (Exhibit 25 of Niren Murthy Deposition)
61.	July 21, 2025 Declaration of Robert Prud'homme
62.	February 14, 2025 Responsive Expert Report of Alex M. Brill
63.	February 14, 2025 Rebuttal Expert Report of Peter J. Pitts
64.	Non-Confidential Opening Brief of Cross-Appellant Protiva Biotherapeutics, Inc., Case No. 20-1184, Dkt. 67-1
65.	Patent Owner's Response Pursuant to 37 C.F.R. § 42.107, IPR2019-00554, Paper No. 15
66.	Declaration of David H. Thompson, Ph.D., IPR2019-00554, Ex. 2004

Ex. No.	Description
67.	Patent Owner's Response Pursuant to 37 C.F.R. § 42.120, IPR2018-00739, Paper No. 24
68.	Plaintiff Arbutus Biopharma Corporation's Responses and Objections to Defendants Moderna, Inc. and ModernaTX, Inc's Second Set of Requests for Admission (Nos. 9-44)
69.	Plaintiff Genevant Sciences GMBH's Responses and Objections to Defendants Moderna, Inc. and ModernaTX, Inc's Second Set of Requests for Admission (Nos. 9-44)
70.	November 12, 2009 Filings from the U.S. Patent No. 8,058,069 Prosecution History
71.	June 1, 2010 Filings from the U.S. Patent No. 8,058,069 Prosecution History
72.	January 31, 2011 Filings from the U.S. Patent No. 8,058,069 Prosecution History
73.	July 30, 2010 Filings from the U.S. Patent No. 8,058,069 Prosecution History
74.	May 12, 2011 Filings from the U.S. Patent No. 8,058,069 Prosecution History
75.	August 11, 2011 Filings from the U.S. Patent No. 8,058,069 Prosecution History
76.	October 5, 2011 Filings from the U.S. Patent No. 8,492,359 Prosecution History
77.	March 28, 2012 Filings from the U.S. Patent No. 8,492,359 Prosecution History
78.	August 18, 2014 Filings from the U.S. Patent No. 9,364,435 Prosecution History
79.	February 26, 2015 Filings from the U.S. Patent No. 9,364,435 Prosecution History
80.	Plaintiff Arbutus Biopharma Corporation's First Supplemental Responses and Objections to Defendants Moderna, Inc. and ModernaTX, Inc.'s Fourth Set of Interrogatories (Nos. 14-17)
81.	Plaintiff Genevant Sciences GMBH's First Supplemental Responses and Objections to Defendants Moderna, Inc. and ModernaTX, Inc.'s Fourth Set of Interrogatories (Nos. 14-17)

I. GENERAL FACTS

1. On February 28, 2022, Plaintiffs Arbutus and Genevant filed this lawsuit against Moderna, alleging Moderna's COVID vaccine infringes the '069 patent, '359 patent, '668 patent, '435 patent, '651 patent, and '378 patent. D.I. 1. Since filing this lawsuit, and in accordance with the Court's order narrowing patents and claims, D.I. 475, Plaintiffs have narrowed their infringement allegations to the following patents and claims[2]:

- Claims 7, 9, 11, 13, and 14 of the '651 patent
- Claims 7 and 12 of the '359 patent;
- Claims 7, 8, and 16 of the '435 patent;
- Claims 2, 7, 13, 18, and 19 of the '378 patent.

See Ex. 14 (June 3, 2025 Letter from F. Elenberg) at 1.

2. Each of the asserted claims depend from claim 1 of each respective patent. *See* Ex. 4 ('651 patent) claims; Ex. 5 ('359 patent) claims; Ex. 6 ('435 patent) claims; Ex. 7 ('378 patent) claims.

II. FACTS RELATED TO 28 U.S.C. § 1498

A. U.S. Government Response to the COVID-19 Pandemic

3. After detection of COVID-19 in the United States, the Secretary of Health and Human Services declared a public health emergency on January 31, 2020, under 42 U.S.C. § 247(d). Ex. 8 (MRNA-GEN-02657322) at 322.[3]

[2] For the convenience of the Court, Appendix A, directly following this Statement of Undisputed Facts, lists the asserted claims and their corresponding text.

[3] Unless otherwise specified, page citations of documents with bates numbering use the last three digits of the bates numbering.

4. On March 13, 2020, the White House later declared that the COVID-19 outbreak in the United States constituted a national emergency, post-dating the start of the emergency to March 1, 2020. Ex. 8 (MRNA-GEN-02657322) at 323.

5. On April 16, 2020, Moderna entered into a grant agreement, the C-34 Contract, with the Biomedical Advanced Research and Development Authority ("BARDA") to support the clinical development of a COVID-19 vaccine. Ex. 9 (C-34 Contract).

6. In the C-34 Contract, the U.S. Government acknowledged that "[d]eveloping and delivering a vaccine for highly transmissible, emerging diseases such as the SAR-CoV-2 [*sic*] virus requires breaking from traditional approaches." Ex. 9 (C-34 Contract) at 775. The U.S. Government further described the "critical" importance of domestic production of the COVID-19 vaccine, stating that "[d]omestic production of the vaccine is the only assurance that Americans will have access to the finished product." Ex. 9 (C-34 Contract) at 775.

7. BARDA chose to partner with Moderna to develop the COVID-19 vaccine because "Moderna's mRNA-based vaccine platform has been used to rapidly prepare vaccine candidates against Cytomegalovirus, Zika, Respiratory Syncytial Virus, Influenza, Human Metapneumovirus and Parainfluenza virus." Ex. 9 (C-34 Contract) at 775.

8. On May 15, 2020, the Trump Administration initiated Operation Warp Speed (led by the Departments of Health and Human Services and Defense), through which the U.S. Government and private companies worked together to develop and bring COVID-19 vaccines to the American public as quickly as possible. Ex. 10 (MRNA-GEN-02696526) at 527–530.

9. The U.S. Government adopted a centralized distribution plan for vaccine doses manufactured in connection with Operation Warp Speed. Ex. 11 (MRNA-GEN-02676917) at 920.

10. Specifically, the U.S. Government exercised an option in a preexisting contract with McKesson to deliver specific amounts of vaccine to various locations across the country. Ex. 11 (MRNA-GEN-02676917) at 920.

11. "Centralized distribution allow[ed] the government full visibility, control, and ability to shift assets and use data to optimize vaccine uptake." Ex. 11 (MRNA-GEN-02676917) at 920.

12. The U.S. Government pledged that "no American will be charged for either the COVID-19 vaccine or its distribution." Ex. 11 (MRNA-GEN-02676917) at 923.

13. Moderna was one of a handful of companies selected to participate in Operation Warp Speed. Ex. 12 (MRNA-GEN-02676415) at 416–18; Ex. 13 (MRNA-GEN-02670803) at 803–04.

B. C-100 Contract

14. On August 9, 2020, Moderna entered into a supply contract, the C-100 Contract, with the Army Contracting Command of the U.S. Department of Defense. Ex. 1 (C-100 Contract); Ex. 15 (Bennett Dep. Tr.) at 255:5–12.

15. The first draft of the agreement that became the C-100 Contract, provided by the U.S. Government to Moderna, contained Federal Acquisition Regulation ("FAR") clause 52.227-1, providing the U.S. Government's authorization and consent. Ex. 16 (C-100 Contract Draft) at 626; *see also* Ex. 15 (Bennett Dep. Tr.) at 265:15–268:7 ("Q. This provision was included in the list of incorporated references in the first proposal that went over to Moderna, became the C0100 contract? A. Yes.").

16. The C-100 Contract provided that Moderna would supply at least 100 million doses that the U.S. Government would "own," to "be distributed and used as part of a COVID-19

vaccination campaign" coordinated by the U.S. Government and made "available to the American people at no cost." Ex. 1 (C-100 Contract) at 302; Ex. 13 (MRNA-GEN-02670803) at 803–04.

17. In evaluating Moderna's proposal for the supply contract, the U.S. Government stated that "Moderna is uniquely positioned to have an immediate impact on the United States' COVID-19 pandemic because it is one of the further along among COVID-19 vaccine candidates, having generated promising Phase I clinical data and existing development agreements with the United States Government." Ex. 17 (DOD_000003510) at 512.

18. The C-100 Contract obligated Moderna to produce and supply 100 million doses of COVID-19 vaccine to the U.S. Government. Ex. 1 (C-100 Contract) at 302. The C-100 Contract gave the Government the option to purchase additional doses of COVID-19 vaccine. *Id.*

19. Moderna and the U.S. Government later executed three amendments in which the U.S. Government exercised options for additional doses provided under the C-100 contract. Ex. 18 (C-100 Contract, Option 1 Exercise); Ex. 19 (C-100 Contract, Option 2 Exercise); Ex. 20 (C-100 Contract, Options 3–4 Exercise).

20. The C-100 Contract contains the following clause titled "A.1" (Ex. 1 at 285):

> **A.1** The U.S. Army Contracting Command - Aberdeen Proving Ground (ACC-APG), Natick Division has a requirement for up to 500 million SARS-CoV-2 mRNA-1273 Vaccine doses (100 µg) in support of Joint Program Executive Office - Chemical Biological Radiological Nuclear Defense (JPEO-CBRND), the Assistant Secretary for Preparedness and Response (ASPR), and Biomedical Advanced Research and Development Authority (BARDA). All doses of mRNA-1273 Vaccine referenced herein are 100 µg doses. All doses will be delivered in a multi- dose vial with a volume sufficient for 10 doses per vial.

21. The C-100 Contract contains the following clause titled "C.1 Scope" (Ex. 1 at 302):

STATEMENT OF WORK
LARGE SCALE PRODUCTION OF SARS-CoV-2 VACCINE

C.1 **SCOPE**. The Department of Defense and Health and Human Services (HHS) require large scale manufacturing of vaccine doses in support of the national emergency response to the Coronavirus Disease 2019 (COVID-19) for the United States Government (USG) and the US population.

C.1.1 Background. In December 2019, a novel coronavirus now known as SARS-CoV-2 was first detected in Wuhan, Hubei Province, People's Republic of China, causing outbreaks of the coronavirus disease COVID-19 that has now spread globally. The Secretary of Health and Human Service declared a public health emergency on January 31, 2020, under section 319 of the Public Health Service Act (42 U.S.C. 247d), in response to COVID-19. On March 1, 2020, the President of the United States, pursuant to sections 01 and 301 of the National Emergencies Act (50 U.S.C. 1601 et seq.) and consistent with section 1135 of the Social Security Act (SSA), as amended (42 U.S.C. 1320b-5), proclaimed that the COVID-19 outbreak in the United States constitutes a national emergency.

C.1.1.1 Under Operation Warp Speed (OWS), the Department of Defense and HHS are leading a whole of nation effort to ensure development of promising vaccine, diagnostic and therapeutic candidates and ensure that these medical countermeasures are available in the quantities required to reduce SARS-CoV-2 transmission, identify prior and/or current infection, and improve patient care, thereby mitigating the impact of COVID-19 on the nation and its people. The DoD Joint Program Executive Office for Chemical, Biological, Radiological and Nuclear Defense (JPEO-CBRD) is providing expertise and contracting support to HHS, in compliance with PL 115-92 Authorization Letter for DoD Medical Priorities, through an Interagency Agreement, signed April 23, 2020. As OWS products progress to clinical trials to evaluate the safety and efficacy of vaccines and therapeutics, it is critical that, in parallel, the USG supports large scale manufacturing so that vaccine doses or therapeutic treatment courses are immediately available for nationwide access as soon as a positive efficacy signal is obtained and the medical countermeasures are authorized for widespread use.

C.1.2 Objective: The objective of this effort is to obtain the following:

a. Base Period: Large scale manufacturing of 100 million vaccine doses
b. Option Period 1: Large scale manufacturing of 100 million vaccine doses
c. Option Period 2: Large scale manufacturing of 100 million vaccine doses
d. Option Period 3: Large scale manufacturing of 100 million vaccine doses
e. Option Period 4: Large scale manufacturing of 100 million vaccine doses

The Base Period is 9 months, with overlapping options for a total of 20 months if all options are exercised.

22. The C-100 Contract contains two FAR clauses providing the U.S. Government's authorization and consent: FAR 52.227-1 and FAR 52.227-1, Alternate I. Ex. 1 (C-100 Contract) at 329.

23. FAR 52.227-1 states:

> (a) The Government authorizes and consents to all use and manufacture, in performing this contract or any subcontract at any tier, of any invention described in and covered by a United States patent—
>
> (1) Embodied in the structure or composition of any article the delivery of which is accepted by the Government under this contract; or
>
> (2) Used in machinery, tools, or methods whose use necessarily results from compliance by the Contractor or a subcontractor with (i) specifications or

> written provisions forming a part of this contract or (ii) specific written instructions given by the Contracting Officer directing the manner of performance. the entire liability to the Government for infringement of a United States patent shall be determined solely by the provisions of the indemnity clause, if any, included in this contract or any subcontract hereunder (including any lower-tier subcontract), and the Government assumes liability for all other infringement to the extent of the authorization and consent hereinabove granted.
>
> (b) The Contractor shall include the substance of this clause, including this paragraph (b), in all subcontracts that are expected to exceed the simplified acquisition threshold, as defined in Federal Acquisition Regulation (FAR) 2.101 on the date of subcontract award. However, omission of this clause from any subcontract, including those at or below the simplified acquisition threshold, as defined in FAR 2.101 on the date of subcontract award, does not affect this authorization and consent.

48 CFR § 52.227-1.

24. FAR 52.227-1, Alternate I states:

> (a) The Government authorizes and consents to all use and manufacture of any invention described in and covered by a United States patent in the performance of this contract or any subcontract at any tier.
>
> (b) The Contractor shall include the substance of this clause, including this paragraph (b), in all subcontracts that are expected to exceed the simplified acquisition threshold, as defined in Federal Acquisition Regulation (FAR) 2.101 on the date of subcontract award. However, omission of this clause from any subcontract, including those at or below the simplified acquisition threshold, as defined in FAR 2.101 on the date of subcontract award, does not affect this authorization and consent.

48 CFR § 52.227-1, Alt. I.

25. Moderna received Emergency Use Authorization for its COVID-19 vaccine in the U.S. from the FDA on December 18, 2020. Ex. 23 (MRNA-GEN-02463357) at 358; D.I. 1 at 7.

26. The Emergency Use Authorization allowed the vaccine to be distributed and administered as a medical countermeasure for COVID-19. Ex. 23 (MRNA-GEN-02463357) at 359; Ex. 24 (MRNA-GEN-02677440) at 440.

27. The Emergency Use Authorization conditions specified that Moderna would supply the vaccine to be distributed "as directed by the U.S. government." Ex. 23 (MRNA-GEN-02463357) at 359.

28. Under the C-100 Contract, "Moderna supplied vaccine to the CDC at one of two distribution depots in the United States. Once that product was delivered to the depots, the CDC took responsibility for allocating that product among the jurisdictions and distributing that to jurisdictions." Ex. 15 (Bennett Dep. Tr.) at 347:19–348:4; *see also* Ex. 25 (Thomas Dep. Tr.) at 32:19–22 ("Moderna would provide vaccine to the U.S. government distribution hubs. The U.S. government would then distribute to the vaccination sites.").

29. The C-100 Contract specified that lots of the COVID-19 vaccine would be accepted by the U.S. Government when Moderna produced a certificate of analysis confirming that the lot met the U.S. Government's technical requirements. Ex. 1 (C-100 Contract) at 308; Ex. 22 (Thomas Decl.) ¶ 6.

30. The C-100 Contract specified that lots may be accepted by the U.S. Government while stored for the U.S. Government at Moderna's facilities or accepted upon delivery to a U.S.-designated location. Ex. 1 (C-100 Contract) at 303, 312–316; Ex. 25 (Thomas Dep. Tr.) at 125:1–126:6. Not all doses that were sold under the C-100 Contract were ultimately directed by the U.S. Government to be shipped to U.S. Government-designated location. Ex. 25 (Thomas Dep. Tr.) at 147:21–153:15; Ex. 26 (Santoli Dep. Tr.) at 52:6–53:4; Ex. 27 (Johnson Dep. Tr.) at 92:2–18; Ex. 22 (Thomas Decl.) ¶¶ 4–7.

31. The doses manufactured, released, sold and delivered to the U.S. Government-designated sites under the C-100 Contract were tracked in U.S. Government batch trackers. Ex. 40 (MRNA-GEN-00459217); Ex. 22 (Thomas Decl.) ¶¶ 4–7.

32. The number of COVID-19 doses accepted by the U.S. Government and sold is reflected in Moderna's sales data. Ex. 28 (C-100 Doses Spreadsheet). In total, Moderna sold 500,001,540 doses of COVID-19 vaccine to the U.S. Government under the C-100 Contract. Ex. 28 (C-100 Doses Spreadsheet) at Column E (identifying doses shipped to Government under C-100 Contract); Ex. 25 (Thomas Dep. Tr.) at 74:19–77:20 (Moderna's 30(b)(6) witness confirming that C-100 Doses Spreadsheet "contain[s] all of the sales to the U.S. government under the C-100 contract"); Ex. 22 (Thomas Decl.) ¶ 8; Ex. 29 (Lawton Op. Rpt.) ¶ 1618 (Plaintiffs' damages expert agreeing that 500,001,540 doses were sold to Government pursuant to C-100 Contract).

33. In total, the U.S. Government spent $8,204,861,628 purchasing the C-100 doses from Moderna. Ex. 28 (C-100 Doses Spreadsheet) at Column F (identifying revenue associated with each shipment under the C-100 Contract); Ex. 22 (Thomas Decl.) ¶ 8.

34. Amendment No. P00031 to the C-100 Contract, dated August 9, 2020, modified the total funded value of the C-100 Contract to $8,204,906,278.12. Ex. 21 (MRNA-GEN-00457581); Ex. 22 (Thomas Decl.) ¶ 9.

35. There were various exhibits and executed amendments to the C-100 Contract that Moderna and the U.S. Government produced during discovery. *See, e.g.* MRNA-GEN-00078981; MRNA-GEN-00079015; MRNA-GEN-00079018; MRNA-GEN-00937552; MRNA-GEN-00079041; MRNA-GEN-00079769; MRNA-GEN-00079781; MRNA-GEN-00078997; MRNA-GEN-00079566; MRNA-GEN-00078999; MRNA-GEN-00079001; MRNA-GEN-00079554; MRNA-GEN-00079066; MRNA-GEN-00079013; MRNA-GEN-00079122; MRNA-GEN-00079540; MRNA-GEN-00079351; MRNA-GEN-00079514; MRNA-GEN-00079367; MRNA-GEN-00078969; MRNA-GEN-00078953; MRNA-GEN-00078957; MRNA-GEN-00079245; MRNA-GEN-00079098; MRNA-GEN-00079524; MRNA-GEN-00079268; MRNA-GEN-

00079257; MRNA-GEN-00079232; MRNA-GEN-00079112; MRNA-GEN-00079379; MRNA-GEN-00079384; MRNA-GEN-00079390; MRNA-GEN-00079404; MRNA-GEN-00079512; MRNA-GEN-00079510; MRNA-GEN-00079568; MRNA-GEN-00456319; MRNA-GEN-00456332; MRNA-GEN-00457581. Plaintiffs have not disclosed any factual contentions regarding the exhibits or amendments in connection with § 1498; therefore, Moderna did not attach them to this Motion for Summary Judgment.[4]

C. Additional Benefits to the U.S. Government

36. The U.S. Government's mass vaccination campaign, conducted in part using doses purchased under the C-100 Contract, allowed the U.S. Government to facilitate the reopening and recovery of the country and the economy. Ex. 30-A (Rutherford Op. Rpt.) ¶¶ 62–90; Ex. 31-A (Vellturo Op. Rpt.) ¶¶ 35–52.

37. Both the Trump and Biden White Houses identified bringing a vaccine to the public as a key government objective, with the Biden White House stating that "[t]he health and economic security of our nation depend on it." *E.g.*, Ex. 32 (MRNA-GEN-02673093) at 093; Ex. 10 (MRNA-GEN-02696526) at 527–28; Ex. 33 (Brill Dep. Ex. 3) at 2–4, 6, 8.

38. Specifically, the U.S. Government's mass vaccination campaign resulted in reduced transmission of COVID-19, leading to a decrease in severe infections, hospitalizations, and deaths from COVID-19, as well as healthcare savings to the U.S. Government. Ex. 30-A (Rutherford Op. Rpt.) ¶¶ 74–75; Ex. 34 (MRNA-GEN-02657270) at 270 (estimating $2.95 trillion in healthcare savings as a result of COVID-19 vaccines).

39. Dr. Rutherford, a renowned public health expert with decades of experience in federal, state, and local public health departments, explained the federal government's

[4] Nevertheless, Moderna is able to provide these to the Court if desired and reserves the right to rely on these in reply if Plaintiffs raise any undisclosed contentions.

longstanding role in safeguarding the public health. Ex. 30-A (Rutherford Op. Rpt.) ¶¶ 27–35. COVID-19 vaccines like Moderna's enabled the Government to achieve this objective by implementing a mass vaccination program, allowing society to reopen and recover. Ex. 30-A (Rutherford Op. Rpt.) ¶¶ 62–90; Ex. 31-A (Vellturo Op. Rpt.) ¶¶ 35–52.

40. By December 2021, the Government estimated that the vaccines were associated with 213,000 fewer deaths, 1.38 million fewer hospitalizations, and 25.32 million fewer cases. Ex. 34 (MRNA-GEN-02657270) at 270, 278–84.

41. The Government also estimated that COVID-19 vaccines saved approximately $2.95 trillion in healthcare and economic costs. Ex. 34 (MRNA-GEN-02657270) at 270, 285–86.

42. Dr. Vellturo, an economist, calculated that the C-100 Contract saved the Government approximately $8 billion in costs associated with COVID-19 hospitalizations in 2021 alone, covering the total cost of the contract to the Government. Ex. 31-A (Vellturo Op. Rpt.) ¶¶ 35–52.

43. One of the U.S. Government's strategies in entering the C-100 Contract was to "allow[] for consideration for international assistance if doses obtained exceed what is necessary for the US." Ex. 35 (HHS-0000414) at 415.

44. In addition to the immediate benefit of securing sufficient doses available for the Government to deploy across the United States, the Government's procurement of COVID-19 vaccine under the C-100 Contract allowed the Government to ship doses abroad. Ex. 30-A (Rutherford Op. Rpt.) ¶¶ 80–85.

45. Discovery from the Government confirms its strategy in contracting for the doses was to "allow[] for consideration for international assistance if doses obtained exceed what is necessary for the US." Ex. 35 (HHS-0000414) at 415.

46. The policy benefits of this strategy are twofold: the Government was able to use the COVID-19 vaccine as an important foreign policy tool while simultaneously safeguarding the United States and its people by reducing the global spread of COVID-19. Ex. 30-B (Rutherford Reply Rpt.) ¶¶ 41–42.

47. Acquiring excess doses of COVID-19 vaccine under the C-100 Contract allowed the U.S. Government to provide vaccine doses to developing countries, fulfilling foreign diplomacy objectives and slowing the global spread of COVID-19. Ex. 30-A (Rutherford Op. Rpt.) ¶¶ 80–85; Ex. 30-B (Rutherford Reply Rpt.) ¶¶ 41–42.

48. The Government engaged in vaccine diplomacy by donating vaccines directly to developing countries and provided doses to international partners through programs like COVAX, the United Nations-sponsored program to bring COVID-19 vaccines to the world. Ex. 36 (MRNA-GEN-02669317).

49. In 2021, the White House described the United States's provision of COVID-19 vaccines to the world as "American leadership on a global stage" and the "need to reassert America's leadership in the world in the fight against this and future public health threats." Ex. 37 (MRNA-GEN-02119128) at 155; Ex. 38 (MRNA-GEN-02670578) at 581.

50. The White House considered this strategy vital to national security because "ending this pandemic means ending it everywhere" and "[a]s long as this pandemic is raging anywhere in the world, the American people will still be vulnerable." Ex. 39 (GENV-01086629) at 629.

51. Dr. Christopher Vellturo calculated that the C-100 Contract resulted in $8.13–8.21 billion in Medicare and Medicaid savings from estimated reductions in COVID-19 hospitalizations in calendar year 2021 alone. Ex. 31-A (Vellturo Op. Rpt.) ¶ 42; Ex. 31-B (Vellturo Reply Rpt.) ¶¶ 40–41.

52. The savings in 2021 alone approximately offset the total cost of the C-100 Contract, benefitting the U.S. Government. Ex. 31-A (Vellturo Op. Rpt.) ¶ 42; Ex. 31-B (Vellturo Reply Rpt.) ¶¶ 40–41.

53. The mass vaccination campaign carried out by the U.S. Government resulted in an increase in income tax receipts of $32 billion in 2021 alone and an increase of $112 billion over a 3.5-year period. Ex. 31-A (Vellturo Op. Rpt.) ¶ 52.

54. Dr. Vellturo calculated Moderna's approximate share of the estimated increase in federal individual income tax receipts to be $41 billion over the 3.5-year period. Ex. 31-A (Vellturo Op. Rpt.) ¶ 52 n.160.

55. "The impact of the COVID-19 pandemic, one of the greatest public health challenges in modern history, would be immeasurably worse but for the rapid, widespread availability of cutting-edge mRNA-based vaccines like Moderna's." D.I. 1 at 1.

III. FACTS RELATED TO PLAINTIFFS' DOE THEORY

A. Prosecution History

56. The '069 patent's application was the first filed application in the Ratio Patent family. The '069 patent is the parent to all other Ratio Patents. *E.g.*, Ex. 7 ('378 patent) Cover.

57. Prior to review by the Examiner, the applicants of the '069 patent submitted amended claims on November 12, 2009. Ex. 70 (Nov. 12, 2009 – '069 PH) (referred to herein as the "original claims" or "original-filed claims" of the '069 patent).

58. Original claim 1 of the '069 patent recited:

1. (Previously presented) A nucleic acid-lipid particle comprising:

(a) a nucleic acid;

(b) a cationic lipid comprising from about 50 mol % to about 65 mol % of the total lipid present in the particle;

(c) a non-cationic lipid comprising a mixture of a phospholipid and cholesterol or a derivative thereof, wherein the phospholipid comprises from about 4 mol % to about 10 mol % of the total lipid present in the particle and the cholesterol or derivative thereof comprises from about 30 mol % to about 40 mol % of the total lipid present in the particle; and

(d) a conjugated lipid that inhibits aggregation of particles comprising from about 0.5 mol % to about 2 mol % of the total lipid present in the particle.

Ex. 70 (Nov. 12, 2009 – '069 PH) at 4; *see also* Ex. 71 (June 1, 2010 – '069 PH) at 2.

59. During prosecution, the applicants agreed that claim 1 of the '069 patent was illustrative of the pending claims. Ex. 72 (Jan. 31, 2011 – '069 PH) at 9.

60. In July 2010, the Examiner rejected the pending claims as obvious and unpatentable in view of US2006/0008910 ("MacLachlan"). Ex. 73 (July 30, 2010 – '069 PH) at 3–7; Ex. 57 (MacLachlan).

61. The Examiner found that "MacLachlan also teaches the SNALP wherein the cationic lipid is from about 2 mol % to about 60 mol % of the total lipid present in the particle (paragraph 85), the phospholipid is from about 5% to about 90% or from about 10% to about 85% of the total lipid present in the particle (paragraph 85), the cholesterol is from about 20% to about 55% of the total lipid present in the particle (paragraph 85, top of page 8), and the conjugated lipid is from about 1% to about 20% of the total lipid present in the particle (paragraph 85)." Ex. 73 (July 30, 2010 – '069 PH) at 4.

62. The Examiner concluded that "[i]t would have been obvious to one of skill in the art at the time the instant invention was made to make a nucleic acid lipid particle comprising an siRNA, a cationic lipid, a phospholipid, cholesterol, and a PEG-conjugate because MacLachlan

teaches such a particle," and "[i]t further would have been obvious to formulate the particles with the instantly claimed amounts of the individual components because MacLachlan teaches particles formulated with ranges of amounts that overlap with the instantly claimed ranges and teaches that the proportions of the components can be varied by those of skill in the art." Ex. 73 (July 30, 2010 – '069 PH) at 4–5.

63. The applicants responded to the Examiner's rejection by "submit[ting] that the presently claimed SNALP formulations, which are referred to in the specification as '1:57 SNALP,' have new and unexpected results." Ex. 72 (Jan. 31, 2011 – '069 PH) at 8; *see also id.* at 9-11

64. The applicants explained that "Figure 3 of Example 4 demonstrates that 1:57 SNALP formulations were significantly ***more efficacious*** as compared to a nucleic acid-lipid particle previously described ('2:30 SNALP')," and "Figure 2 of Example 3 demonstrates that the 1:57 SNALP formulations were substantially ***more effective*** at silencing the expression of a target gene as compared to nucleic acid-lipid particles previously described ('2:40 SNALP,' wherein the cationic lipid is present in the formulation at about 40 mol %)." Ex. 72 (Jan. 31, 2011 – '069 PH) at 10 (emphasis in original).

65. According to applicants, these "new and unexpected results [we]re more than sufficient to rebut a presumption of obviousness based on MacLachlan et al." Ex. 72 (Jan. 31, 2011 – '069 PH) at 11; Ex. 57 (MacLachlan).

66. In May 2011, the Examiner rejected the claims a second time[5]—this time the Examiner rejected the pending claims as anticipated by MacLachlan. Ex. 74 (May 12, 2011 – '069 PH) at 2–4 (claim 5 was still rejected as obvious in view of MacLachlan); Ex. 57 (MacLachlan).

67. The Examiner stated that "[t]he claims are to a nucleic acid lipid particle comprising a nucleic acid, a cationic lipid, a non-cationic lipid mixture of phospholipid and cholesterol, and a conjugated lipid. The claims are further directed to the particle wherein the nucleic acid is a siRNA, the relative amounts of components read on a broad range of amounts because of the term 'comprising about'. The applicants do not provide a definition of the term in the specification. Thus, 'comprising about' could embrace an amount +/- 10, 20, 30 mol % of a lipid component." Ex. 74 (May 12, 2011 – '069 PH) at 2.

68. The Examiner found that "MacLachlan also teaches the SNALP wherein the cationic lipid is from about 2 mol % to about 60 mol % of the total lipid present in the particle (paragraph 85), the phospholipid is from about 5% to about 90% or from about 10% to about 85% of the total lipid present in the particle (paragraph 85), the cholesterol is from about 20% to about 55% of the total lipid present in the particle (paragraph 85, top of page 8), and the conjugated lipid is from about 1% to about 20% of the total lipid present in the particle (paragraph 85)." Ex. 74 (May 12, 2011 – '069 PH) at 3.

69. The Examiner compared the pending mol % range limitations to the disclosures in paragraph [0085] of MacLachlan:

[5] The Examiner changed in between the first and second Non-Final Rejection. *See* Ex. 74 (May 12, 2011 – '069 PH) at 2.

instant claims of '367	pre-grant US publication (paragraph 0085)
1) cationic lipid comprising from about 50-65 mol %	1) cationic lipid 2-60, 5-50, 10-45, 20-40, 30 mol%
2) phospholipid comprises from about 4-10 mol %	2) phospholipid 5-90 mol%
3) cholesterol comprising from about 30-40 mol%	3) cholesterol 20-55 mol %
4) conjugated lipid comprising from about 0.5-2 mol%	4) conjugated lipid 1-20 mol %

Ex. 74 (May 12, 2011 – '069 PH) at 3–4; Ex. 57 (MacLachlan).

70. The Examiner stated that he "fully considered" applicant's January 31, 2011 arguments but found "they [we]re not persuasive." Ex. 74 (May 12, 2011 – '069 PH) at 6.

71. The Examiner also responded to the applicants' statements that the claims were directed to a "1:57 SNALP formulation and their new and unexpected results": "[T]he argument is not found persuasive because while it is acknowledged that 1:57 shows a new and unexpected result, the product recited in the instant claims read on broad range of SNALP formulations, including 2:30 and 2:40 because of the term 'comprising from about'. The term is broad because the specification does not provide a definition of the term and the term could read on SNALP formulations other than 1:57, e.g., 2:30 and 2:40." Ex. 74 (May 12, 2011 – '069 PH) at 6.

72. In response, and after multiple interviews with the Examiner, the applicants amended the pending claims to remove "about" from the mol % range limitations. *See* Ex. 75 (Aug. 11, 2011 – '069 PH) at 2–9.

73. Claim 1 of the '069 patent was amended as follows:

1. (Currently amended) A nucleic acid-lipid particle comprising:

(a) a nucleic acid;

(b) a cationic lipid comprising from ~~about~~ 50 mol % to ~~about~~ 65 mol % of the total lipid present in the particle;

(c) a non-cationic lipid comprising a mixture of a phospholipid and cholesterol or a derivative thereof, wherein the phospholipid comprises from ~~about~~ 4 mol % to ~~about~~ 10 mol % of the total lipid present in the particle and the cholesterol or derivative thereof comprises from ~~about~~ 30 mol % to ~~about~~ 40 mol % of the total lipid present in the particle; and

(d) a conjugated lipid that inhibits aggregation of particles comprising from ~~about~~ 0.5 mol % to ~~about~~ 2 mol % of the total lipid present in the particle.

Ex. 75 (Aug. 11, 2011 – '069 PH) at 2.

74. The applicants submitted remarks with the claim amendments, stating that "[i]n making both [the anticipation and obviousness] rejections, the Examiner alleges that the term 'comprising from about' recited in the instant claims embraces a broad range of lipid components. In an earnest effort to expedite prosecution, but without acquiescing on the merits of the rejection, Applicants have amended the claims to delete 'about' from the ranges of lipid components recited therein." Ex. 75 (Aug. 11, 2011 – '069 PH) at 7.

75. Applicants provide[d] a comparison of the ranges of lipid components between claim 1 of the '069 patent application as amended and the lipid ranges of MacLachlan:

Lipid Component	Claim 1 as Amended	US 2006/0008910*
Cationic Lipid	50-65 mol %	"2-60, 5-50, 10-45, 20-40, 30 mol%"
Phospholipid	4-10 mol %	"5-90 mol%"
Cholesterol	30-40 mol %	"20-55 mol %"
Conjugated Lipid	0.5-2 mol %	"1-20 mol %"

*The ranges set forth in this column are reproduced from page 4 of the Office Action mailed May 12, 2011.

Ex. 75 (Aug. 11, 2011 – '069 PH) at 8; Ex. 57 (MacLachlan).

76. "Applicants respectfully point[ed] out that claim 1 as presently amended recites narrow ranges for each of the lipid components compared to the substantially broader ranges taught by MacLachlan *et al*." Ex. 75 (Aug. 11, 2011 – '069 PH) at 8.

77. The applicants stated: "SNALP formulations having increased amounts of cationic lipid such as, *e.g.*, the 1:57 SNALP formulation, provide ***unexpectedly superior advantages*** over previously exemplified SNALP formulations containing lower amounts of cationic lipid." Ex. 75 (Aug. 11, 2011 – '069 PH) at 10 (emphasis in original); *see also id.* at 9.

78. The applicants stated: "Figure 3 of Example 4 demonstrates that 1:57 SNALP formulations were significantly ***more efficacious*** as compared to a nucleic acid-lipid particle previously described ('2:30 SNALP')," and "Figure 2 of Example 3 demonstrates that the 1:57 SNALP formulations were substantially ***more effective*** at silencing the expression of a target gene as compared to nucleic acid-lipid particles previously described ('2:40 SNALP,' wherein the cationic lipid is present in the formulation at 40 mol %)." Ex. 75 (Aug. 11, 2011 – '069 PH) at 9-10 (emphasis in original).

79. After the '069 patent issued, the applicants filed the four other Ratio Patents that were asserted in this case. Each of the Ratio Patents has claims with mol % range limitations. *See* Ex. 5 ('359 patent); Ex. 3 ('668 patent); Ex. 6 ('435 patent); Ex. 7 ('378 patent).

80. The original-filed claims of the '359 patent contained the word "about" in the mol % range limitations, but the applicants amended those claims and removed the word "about." *Compare* Ex. 76 (Oct. 5, 2011 – '359 PH) at 114 (claim 1 reciting "a cationic lipid comprising from ***about*** 50 mol % to ***about*** 85 mol %" and "a conjugated lipid . . . comprising from ***about*** 0.5 mol % to ***about*** 2 mol %" (emphasis added)), *with* Ex. 77 (Mar. 28, 2012 – '359 PH) at 4

(cancelling claim 1 and adding claim 47 that recites "a cationic lipid comprising from 50 mol % to 65 mol %" and "a conjugated lipid . . . comprising from 0.5 mol % to 2 mol %" without "about").

81. The original-filed claims of the '435 patent contained the word "about" in the mol % range limitations, but applicants amended these claims by removing the word "about." *Compare* Ex. 78 (Aug. 18, 2014 – '435 PH) at 114 (claim 1 reciting "a cationic lipid comprising from ***about*** 50 mol % to ***about*** 85 mol %," "a non-cationic lipid comprising from ***about*** 13 mol % to ***about*** 49.5 mol %," and "a conjugated lipid . . . comprising form ***about*** 0.5 mol % to ***about*** 2 mol %" (emphasis added)), *with* Ex. 79 (Feb. 26, 2015 – '435 PH) at 2 (cancelling claim 1 and adding claim 47 that recites "a cationic lipid comprising from 50 mol % to 85 mol %," "a non-cationic lipid comprising from 13 mol % to 49.5 mol %," and "a conjugated lipid . . . comprising form 0.5 mol % to 2 mol %" without "about").

B. Claim Construction Proceedings

82. This Court and Plaintiffs acknowledged during claim construction that removing "about" from the pending claims during prosecution resulted in a disclaimer. *See* D.I. 266 at 18 ("[T]he presence of the word 'about' in the specification without its similar inclusion in the claim language could support a construction that eliminates a broader range of approximation, but it does not preclude application of the scientific convention of rounding."); *id.* at 21 ("Plaintiffs contend that during prosecution, they only disclaimed the broader variability that was encompassed by the term 'about.'"); *id.* at 21–22; Ex. 41 (2024-02-08 *Markman* Tr.) at 35–44.

83. Under Plaintiffs' application of the Court's claim construction, the mol % range limitations were expanded as follows (using claim 1 of the '069 patent as an example):[6]

[6] This table only contains the modifications to the mol % range limitations asserted under Plaintiffs' doctrine-of-equivalents theories. *See* Section *III.C*, *infra*.

Lipid Component	Mol % Range Claimed	Plaintiffs' Application of the Court's Claim Construction
Cationic Lipid	50 – 65 mol %	49.5 – 65.499 mol %
Phospholipid	4 – 10 mol %	3.5 – 10.499 mol %
Cholesterol	30 – 40 mol %	29.5 – 40.499 mol %
Conjugated Lipid	0.5 – 2 mol%	0.45 – 2.499 mol %

84. Plaintiffs stated that with this construction, to show infringement, they "would need to show . . . that Moderna's product, when they make it or they sell it, has particles -- the Claim is directed to nucleic acid particles -- has particles between 49.5 and 65.49 percent cationic lipid." Ex. 41 (2024-02-08 *Markman* Tr.) at 39:24–40:6 (using the cationic lipid limitation of the '069 patent as an example); *see also id.* at 40:16–41:6; *id.* at 44:2–3.

C. Plaintiffs' DOE Theories

85. Plaintiffs' DOE theories implicate the "mol% range limitations" in the Ratio Patents—i.e., the mol % range of cationic lipid, non-cationic lipid, and conjugated lipid in the total lipid present in the claimed nucleic acid-lipid particle. Ex. 42 (2024-11-25 Mitchell Rep.) at 456, 538–546.

1. "Cationic Lipid" Limitation

86. Plaintiffs' first DOE theory relates to the cationic lipid mol % range limitations in the '359 and '435 patents. *See* Ex. 42 (2024-11-25 Mitchell Rep.) at 481–86. The following is a table of the asserted claims with a cationic lipid mol % range limitation in the '359 and '435 patents:

Patent and Claims	Claim Language
'359 Patent, claim 7	"the cationic lipid comprises from ***50 mol % to 60 mol %*** of the total lipid present in the particle"
'359 Patent, claim 12 (extrapolated from claim 1)	"a cationic lipid comprising from ***50 mol % to 65 mol %*** of the total lipid present in the particle"

'435 Patent, claims 7, 8, and 16 (extrapolated from claim 1)	"a cationic lipid comprising from ***50 mol % to 85 mol %*** of the total lipid present in the particle"

87. Each of the asserted claims with a cationic lipid mol % range limitation have a lower limit of 50 mol %. *See* Ex. 5 ('359 patent) claims 1, 7, 12; Ex. 6 ('435 patent) claims 1, 7, 8, 16.

88. Plaintiffs allege that 44.5 mol %, 45 mol %, 46 mol %, 47 mol %, 48 mol %, 48.5 mol %, and 49 mol % are equivalent to 50 mol % cationic lipid in the mol % range limitations. *See* Ex. 42 (2024-11-25 Mitchell Rep.) at 456, 481–86.

2. "Non-Cationic Lipid" Limitation

89. Plaintiffs' second DOE theory relates to the non-cationic lipid mol % range limitations in the '435 patent. *See* Ex. 42 (2024-11-25 Mitchell Rep.) at 486, 511–513.

90. "Phospholipid" and "cholesterol" are both "non-cationic lipids." The amount of "phospholipid" and "cholesterol" in a nucleic acid-lipid particle is equivalent to the recited total amount of "non-cationic lipid" in the particle.

91. Plaintiffs' second DOE theory applies to the "non-cationic lipid" component in claim 1 of the '435 patent and is incorporated into the dependent claims of the '435 patent. *See* Ex. 42 (2024-11-25 Mitchell Rep.) at 486 n.139.

92. The following is a table of the asserted claims with a non-cationic lipid mol % range limitation in the'435 patent:

Patent and Claims	**Claim Language**
'435 Patent, claims 7, 8, and 16 (extrapolated from claim 1)	"a non-cationic lipid comprising from ***13 mol % to 49.5 mol %*** of the total lipid present in the particle"

93. Each of the asserted claims of the '435 patent with a non-cationic lipid mol % range limitation have an upper limit of 49.5 mol %. *See* Ex. 6 ('435 patent) claims 1, 7, 8, 16.

94. Plaintiffs allege that 53.5 mol %, 53 mol %, 52 mol %, 51 mol %, and 50 mol % are equivalent to 49.5 mol % non-cationic lipid in the mol % range limitations. *See* Ex. 42 (2024-11-25 Mitchell Rep.) at 486, 511–13.

3. "Conjugated Lipid" Limitation

95. Plaintiffs' third DOE theory relates to the "conjugated lipid" mol % range limitations in the '359, '435, and '378 patents. *See* Ex. 42 (2024-11-25 Mitchell Rep.) at 514, 538–42.

96. The following is a table of the asserted claims with a "conjugated lipid" mol % range limitation in the '359, '435, and '378 patents:

Patent and Claims	Claim Language
'359 Patent, claim 7, 12 (extrapolated from claim 1)	"a conjugated lipid . . . comprising from ***0.5 mol % to 2 mol %*** of the total lipid present in the particle"
'435 Patent, claims 7, 8, and 16 (extrapolated from claim 1)	"a conjugated lipid . . . comprising from ***0.5 mol % to 2 mol %*** of the total lipid present in the particle"
'378 Patent, claims 2, 7, 13, 18, and 19	"polyethyleneglycol (PEG)-lipid conjugate consisting of from ***0.1 mol % to 2 mol %*** of the total lipid present in the particle"

97. The '069, '359, and '435 patent claims recite a "conjugated lipid," and the '378 patent recites "a polyethyleneglycol (PEG)-lipid conjugate." *See* Ex. 2 ('069 patent) claim 1; Ex. 5 ('359 patent) claims 1, 7, 12; Ex. 6 ('435 patent) claims 1, 7, 8, 16; Ex. 7 ('378 patent) claims 1, 2, 7, 13, 18, 19.

98. In the context of the Ratio Patents, a "PEG-lipid conjugate" is a "conjugated lipid." *E.g.*, Ex. 7 ('378 patent), 11:62–64 ("SNALP and SPLP typically contain a cationic lipid, a non-cationic lipid, and ***a lipid conjugate (e.g., a PEG-lipid conjugate)***.").

99. Each of the asserted claims with a "conjugated lipid" mol % range limitation have an upper limit of 2 mol %. *See* Ex. 5 ('359 patent) claims 1, 7, 12; Ex. 6 ('435 patent) claims 1, 7, 8, 16; Ex. 7 ('378 patent) claims 1, 2, 7, 13, 18, 19.

100. Plaintiffs allege that 3.5 mol %, 3 mol %, and 2.5 mol % are equivalent to 2 mol % "conjugated lipid" in the asserted mol % range limitations. *See* Ex. 42 (2024-11-25 Mitchell Rep.) at 513, 538–42.

D. Scope of Prosecution Disclaimer

101. The Examiner defined "about" as "+/- 10, 20, 30 mol % of a lipid component" during prosecution of the '069 patent. Ex. 74 (May 12, 2011 – '069 PH) at 2. The applicants did not offer an alternative definition of "about" during prosecution of the Ratio Patents.

102. Plaintiffs agreed during claim construction that the Examiner had defined "about" to mean "+/- 10, 20, 30 mol % of a lipid component." D.I. 170 at 14, 37–38; Ex. 43 (2024-02-08 Plaintiffs' *Markman* Demonstratives) at 32–36; Ex. 41 (2024-02-08 *Markman* Tr.) at 36:4–8, 37:15–20, 38:7–10, 41:18–22.

103. The Court agreed during claim construction that the Examiner had defined "about" to mean "+/- 10, 20, 30 mol % of a lipid component." D.I. 266 at 21–22.

104. The applicants deleted "about" from the original-filed claims of the '069 patent to overcome the Examiners' rejection based on anticipation and obviousness over MacLachlan. *See, e.g.*, Ex. 41 (2024-02-08 *Markman* Tr.) at 35:21–22 ("The Examiner rejected the Claims over a prior art reference called [MacLachlan]."); *id.* at 35:23–36:3, 36:17–20, 42:14–17, 43:15-17; D.I. 170 at 51.

105. The mol % ranges of the four lipid components in the original-filed claims of the '069 patent overlapped with ranges of the four lipid components taught in MacLachlan. *See, e.g.*, Ex. 41 (2024-02-08 *Markman* Tr.) at 35:23–36:3 ("[MacLachlan] disclosed a range for this cationic lipid of 2 to 60. So [MacLachlan] has a wide range of 2 to 60. And what the Examiner said in rejecting over [MacLachlan] is that the Claims as then presented . . . were all so broad, like

[MacLachlan]. And these broad Claims overlapped with each other."); *id.* at 36:17–20, 42:14–17, 43:15-17; D.I. 170 at 51; Ex. 73 (July 30, 2010 – '069 PH) at 4–5; Ex. 57 (MacLachlan).

106. A comparison of the original claims of the '069 patent (with about) to the disclosures in MacLachlan show that each of the lipid component elements in the patent application almost entirely overlaps with MacLachlan:

Lipid Component	Original Claim 1 of the '069 Patent (with "about")	Prior-Art Reference MacLachlan
Cationic Lipid	20 – 95 mol %	2 – 60 mol %
Phospholipid (non-cationic lipid)	0 – 40 mol %	5 – 90 mol %
Cholesterol (non-cationic lipid)	0 – 70 mol %	20 – 55 mol %
Conjugated Lipid	0 – 32 mol %	1 – 20 mol %

107. Plaintiffs agreed that they narrowed the claims during prosecution and to determine the scope of the narrower claims that "you get rid of 'about' and you narrow [the claim]," and that means "you get rid of that plus-or minus 10, 20, 30 [percent]." Ex. 41 (2024-02-08 *Markman* Tr.) at 42:9–17; Ex. 43 (2024-02-08 Plaintiffs' *Markman* Demonstratives) at 36.

108. Thus, the original and amended scope of each asserted Ratio Patent (for the lipid components alleged to have equivalents under Plaintiffs' DOE theories) are as follows:

'359 Patent

Lipid Component	Original Claim 1 (with "about")	Amended Claim 1 (without "about")
Cationic Lipid	20 – 95 mol %	49.5 – 65.49 mol %
Conjugated Lipid	0 – 32 mol %	0.45 – 2.49 mol %

'435 Patent

Lipid Component	Original Claim 1 (with "about")	Amended Claim 1 (without "about")
Cationic Lipid	20 – 100 mol %	49.5 – 85.49 mol %
Non-Cationic Lipid	0 – 79.5 mol %	12.5 – 49.549 mol %
Conjugated Lipid	0 – 32 mol %	0.45 – 2.49 mol %

'378 Patent

Lipid Component	Original Claim 1 (with "about")	Amended Claim 1 (without "about")
Conjugated Lipid	0 – 32 mol %	0.05 – 2.49 mol %

109. The difference between the original claims and the amended claims are as follows:

'359 Patent

Lipid Component	Original Claim 1 (with "about")	Amended Claim 1 (without "about")	Difference between Original and Amended Claims
Cationic Lipid	20 – 95 mol %	49.5 – 65.49 mol %	20 – 49.499 and 65.5 – 95 mol %
Conjugated Lipid	0 – 32 mol %	0.45 – 2.49 mol %	0 – 0.449 and 2.5 –32 mol %

'435 Patent

Lipid Component	Original Claim 1 (with "about")	Amended Claim 1 (without "about")	Difference between Original and Amended Claims
Cationic Lipid	20 – 100 mol %	49.5 – 85.49 mol %	20 – 49.499 and 85.5 – 95 mol %
Non-Cationic Lipid	0 – 79.5 mol %	12.5 – 49.549 mol %	0 – 12.499 and 49.55 – 79.5 mol %
Conjugated Lipid	0 – 32 mol %	0.45 – 2.49 mol %	0 – 0.449 and 2.5 –32 mol %

'378 Patent

Lipid Component	Original Claim 1 (with "about")	Amended Claim 1 (without "about")	Difference between Original and Amended Claims
Conjugated Lipid	0 – 32 mol %	0.05 – 2.49 mol %	0 – 0.049 and 2.5 –32 mol %

110. The table below shows a comparison of (1) the difference between the original and amended claims ("disclaimed territory") relevant to Plaintiffs' DOE theories; (2) Plaintiffs' alleged equivalent for each lipid component; and (3) the disclosure in MacLachlan for each lipid component. Ex. 75 (Aug. 11, 2011 – '069 PH) at 8.

Lipid Component	Disclaimed Territory (relevant to DOE)	Plaintiffs' Alleged Equivalent	Prior Art MacLachlan Disclosure
Cationic Lipid	20 – 49.499 mol %	44.5 – 49 mol %	2 – 60 mol %
Non-Cationic Lipid	49.55 – 79.5 mol %	50 – 53.5 mol %	25 – 100 mol %
Conjugated Lipid	2.5 – 32 mol %	2.5 – 3.5 mol %	1 – 20 mol %

111. For the cationic lipid mol % range limitation, the range that Plaintiffs seek to capture through DOE (i.e., 44.5–50 mol %) was encompassed within the literal scope of the original-filed '069 claim reciting the limitation mol % range limitation with "about." *See* Ex. 42 (2024-11-25 Mitchell Rep.) at 456, 481–86.

112. For the non-cationic lipid mol % range limitation, the range that Plaintiffs seek to capture through DOE (i.e., 49.5–53.5 mol %) was encompassed within the literal scope of the original-filed '435 patent claims reciting the limitation mol % range limitation with "about." *See* Ex. 42 (2024-11-25 Mitchell Rep.) at 481–486, 510–13.

113. For the conjugated lipid mol % range limitation, the range that Plaintiffs seek to capture through DOE (i.e., 2.0–3.5 mol %) was encompassed within the literal scope of the original-filed '069 claim reciting the limitation mol % range limitation with "about." *See* Ex. 42 (2024-11-25 Mitchell Rep.) at 513, 538–42.

114. Each of the ranges of lipids Plaintiffs seek to capture through DOE (i.e., 2.5–3.5 mol % PEG, 44.5–50 mol % cationic lipid, and 49.5–53.5 mol % non-cationic) were encompassed in the ranges taught by prior art MacLachlan. *See* ¶¶ 88, 94, 100 *supra*.

115. Plaintiffs agreed during claim construction that to show infringement they "would need to show . . . that Moderna's product . . . has particles between 49.5 and 65.49 mol percent cationic lipid" based on the removal of "about" from in the amended claims. Ex. 41 (2024-02-08 *Markman* Tr.) at 39:22–40:9 (using claim 1 of the '069 patent as an example).

116. Plaintiffs have only argued that the "tangential relationship" exception applies to rebut the presumption of prosecution history estoppel. Ex. 44 (2024-06-07 Genevant Resp. Rog. 10) at 85; Ex. 45 (2024-06-07 Arbutus Resp. Rog. No. 10) at 85.

IV. FACTS RELATED TO INDEFINITENESS OF "FULLY ENCAPSULATED" LIMITATION OF '651 PATENT

A. U.S. Patent No. 9,504,651

117. The Court construed the term from the '651 patent claims 1, 13, and 14, "wherein at least 70% / at least 80% / about 90% of the mRNA in the formulation is fully encapsulated in the lipid vesicles" as "wherein at least 70% /at least 80% / about 90% of the mRNA in the formulation is fully, as distinct from partially, contained inside the lipid vesicles." D.I. 267; D.I. 266 at 37.

118. The '651 patent defines "lipid encapsulated" to "refer to a lipid formulation which provides a compound with full encapsulation, partial encapsulation, or both." Ex. 4 ('651 patent) at 5:38–40; D.I. 266 at 35.

119. The term "partial encapsulation" only appears in the '651 patent in one place. Ex. 4 ('651 patent) at 5:38–40. "Partially" encapsulated nucleic acid is not defined in the '651 patent—expressly or impliedly.

120. The term "full encapsulation" only appears in the '651 patent in one place. Ex. 4 ('651 patent) at 5:38–40. "Fully" encapsulated nucleic acid is not defined in the '651 patent—expressly or impliedly.

121. Plaintiffs "admit[ted] that mRNA can be partially encapsulated in lipid vesicles where the lipid vesicles are lipid aggregates or micelles where the encapsulated mRNA is contained within a relatively disordered lipid mixture." Ex. 68 (2024-06-07 Arbutus Resp. to RFAs) at 37–38; Ex. 69 (2024-06-07 Genevant Resp. to RFAs) at 37–38.

B. Inconsistent Definitions

1. Genevant/Arbutus Witnesses

122. Ian MacLachlan testified that the difference between "fully" and "partially" encapsulated is that one has material on the outside of the surface of a lipid vesicle. Ex. 47 (MacLachlan Dep. Tr.) at 30:10–19 ("That approach . . . was able to confirm that the results of the dye exclusion assay studies were indicative of what I've just described as full encapsulation to differentiate from partial encapsulation, whereby one may have material that is on the outside or on the surface of a lipid vesicle.").

123. Lloyd Jeffs testified that in "some contexts" "the partial in partial encapsulation refer to a portion of the nucleic acid that is not encapsulated." Ex. 48 (Jeffs Dep. Tr.) at 81:5–8 ("Q. So does the partial in partial encapsulation refer to a portion of the nucleic acid that is not encapsulated? A. In some contexts, you could say that.").

124. Adam Judge testified that he did not know what "partially encapsulated" meant and could "speculate," but did not know a way to test for partial encapsulation. *See, e.g.*, Ex. 49 (Judge Dep. Tr.) at 47:11–12 ("I don't know what you mean by partially encapsulated."), 47:20–23 (Q. "So you have no understanding of what partial encapsulation of a nucleic acid would be? A. I can -- I can speculate."), 48:23–49:2 ("Can you think of any way that you would be able to test for partial encapsulation of nucleic acid? A. That's -- I don't -- I -- I don't know.") (objection omitted), 46:20–49:13.

125. Stephen Reid testified that "partially encapsulated" was not a term typically used in their work and that "partially" was vague and could mean different things. *See, e.g.*, Ex. 50 (Reid Dep. Tr.) at 58:3–7 ("Q. And as a scientist, what does the term 'partially encapsulated' mean? A. As it's – it's not a term we typically use in our work."), 58:13–21 ("Q. But I'm asking for your understanding as a scientist. Is there a scientific meaning to the term 'partially

encapsulated'? THE WITNESS: I mean, 'partially' could mean different things, so it's vague what 'partially' could mean.") (objection omitted).

126. Sunny Jeng testified that he does not distinguish between "encapsulation" and "fully encapsulation." Ex. 51 (Jeng Dep. Tr.) at 64:15–22 ("Q. . . . what does it mean to be fully encapsulated? A. I mean, I see the word 'fully' as an adjective of encapsulation. But in my technical view, I don't have a -- I don't distinguish encapsulation or fully encapsulation.").

127. James Heyes testified that "it's an open question . . . amongst formulators" whether the nucleic acid is something that's both inside and outside the lipid particle. Ex. 52 (Heyes Dep. Tr. IPR2018-00680, Ex. 1026) at 101: 8–14 ("So you said can something be inside or outside? I just -- so what I'm saying is I don't think you can really determine whether siRNA – it's an open question I think amongst formulators when you use the RiboGreen method are you looking at nucleic acid that's both inside and outside as you described or is it something that really is generally out -- completely outside.").

128. Dr. Georg Schuster did not have a definition of "partially encapsulated mRNA." *See, e.g.*, Ex. 53 (Schuster Dep. Tr.) at 169:8–20 ("Q. So sitting here today, you can't define or explain what 'partially encapsulated mRNA' is, right? . . . A. I would not -- I don't have now a definition on 'partially encapsulated.' Q. Do you have a definition of 'fully encapsulated mRNA' as a scientist in the field? . . . A. As I said, I was not asked to work on encapsulation, what it fully means to be partially or fully encapsulated." (objections omitted)).

129. Dr. David Thompson testified that surface-adhered nucleic acid could not be considered "partially" encapsulated nucleic acid. Ex. 54 (Thompson Dep. Tr.) at 136:13–19 ("Q. Would a surface-adhered nucleic acid be considered 'partially encapsulated nucleic acid'? A. No.

Q. Would it be considered "unencapsulated nucleic acid"? A. I wouldn't consider it unencapsulated, simply physisorbed to the surface.").

130. Dr. Niren Murthy's definition of "fully encapsulated" simply repeats the claim construction. Ex. 55 (Murthy Reb. Rep.) ¶ 501.

2. Moderna Witnesses

131. Dr. Robert Prud'homme testified that there is "no real definition of fully encapsulated or how to measure it or what that term means," that "[t]here is no accepted definition in the field as to what partially encapsulated means," and that "'partial' is also unclear as to its explicit definition and certainly unclear on whether one could measure it or not." Ex. 56 (Prud'homme Dep. Tr.) at 180:21–182:21.

132. Dr. Pierre Meulien testified that he did not know the difference between "fully encapsulated" and "partially" encapsulated nucleic acid and that he was not sure what either "fully encapsulated" or "partially" encapsulated meant. Ex. 58 (Meulien Dep. Tr.) at 43:17–44:3.

C. Measurement Methods

133. Plaintiffs have not identified an analytical technique that measures the percentage of "partially" encapsulated nucleic acid such as mRNA in a given formulation, as that term is understood in the '651 Patent.

134. Plaintiffs "state[d] that membrane-impermeable dye exclusion assays using dyes that bind to nucleic acids (e.g., Ribogreen) can be used to measure the percentage of nucleic acid in lipid vesicle formulations that is fully encapsulated in the lipid vesicles in accordance with the '651 patent, which can be confirmed when necessary with orthogonal analyses . . . ." Ex. 80 (2024-06-07 Arbutus Rog Resp.) at 24; Ex. 81 (2024-06-07 Genevant Rog Resp.) at 20.

135. Dr. Murthy agreed that "partially encapsulated" mRNA is a possible state of mRNA encapsulation, and although he said any "partially" encapsulated" would be negligible, he could not define what that meant. Ex. 59 (Murthy Dep. Tr.) at 117:8–118:9.

136. Dr. Murthy could not name any analytical technique to measure the percentage of "partially" encapsulated nucleic acid such as mRNA in a lipid formulation. Ex. 59 (Murthy Dep. Tr.) 124:4–125:21.

137. Dr. Murthy opined that "[e]ncapsulation efficiency is a long-standing and standard analytical technique used to measure the total percent of nucleic acid that is fully encapsulated by lipid vesicles." Ex. 55 (Murthy Reb. Rep.) ¶ 107.

138. Blenke was available online on December 21, 2017. Ex. 60 (Blenke, Murthy Dep. Ex. 25) at 793.

139. Blenke disclosed a systematic evaluation of "seven different methods for quantification of short oligonucleotides that are commonly used in the field of drug delivery." Ex. 60 (Blenke) at 797. Blenke disclosed that there is "a very large heterogeneity in the methods that are used for analyzing oligonucleotide load, encapsulation efficiency and oligonucleotide release." Ex. 60 (Blenke) at Abstract. mRNA is an example of an oligonucleotide. Ex. 4 ('651 patent) at 27:40–43, 28:3–5.

140. Blenke disclosed that results of encapsulation quantification methods differ across seven different and commonly used methods:

Table 2
Encapsulation efficiencies of the three different formulation methods as measured with the seven different quantification methods.

	Nanodrop	Ribogreen®	UPLC (UV)	UPLC (FLR)	Platereader	qPCR (probe)	qPCR (SYBR green)
Formulation #1	29%	26%	28%	47%	50%	11%	13%
Formulation #2	95%	95%	97%	76%	80%	103%	97%
Formulation #3	93%	98%	101%	88%	73%	91%	96%

Ex. 60 (Blenke) at 796 Table 2.

141. Blenke concludes that "Remarkably, when measuring the same sample using different quantification methods, in the most extreme cases differences of up to four times higher than other methods were found," which makes "the comparison between for example, . . . encapsulation efficiency impossible … if different measurement methods are used." Ex. 60 (Blenke) at 796.

142. Figure 4 of Blenke illustrates that depending on the test used, the percentage of nucleic acid encapsulated may be as high as 75 % or as low as 50 %. Ex. 60 (Blenke) at 796 Figure 4 (using sample 4 in the chart as an example).

143. Dr. Murthy testified that the seven methods for measuring percentage encapsulated nucleic acids in a given formulation that are disclosed in the Blenke publication were publicly disclosed by 2002. Ex. 59 (Murthy Dep. Tr.) at 146:4–147:14.

144. Citing the Blenke publication, Dr. Prud'homme explained that "different measures of encapsulation can (and do) lead to different results." Ex. Ex. 61-A (Prud'homme Op. Rep.) ¶ 136.

V. APPENDIX A – ASSERTED PATENT CLAIMS

Below are lists of the remaining asserted claims in this litigation by patent number. Italicized and grey-shaded claims are not asserted but are included in the table because the asserted dependent claims incorporate those limitations. Ex. 14 (June 3, 2025 Letter from F. Elenberg).

A. '359 Patent

Claims 7 and 12 of the '359 patent are currently asserted. Both claims depend from claim 1.

Claim No.	Claim Language
1	*A nucleic acid-lipid particle comprising:* *(a) a nucleic acid;* *(b) a cationic lipid comprising from 50 mol % to 65 mol % of the total lipid present in the particle;* *(c) a non-cationic lipid comprising a mixture of a phospholipid and cholesterol or a derivative thereof, wherein the phospholipid comprises from 3 mol % to 15 mol % of the total lipid present in the particle and the cholesterol or derivative thereof comprises from 30 mol % to 40 mol % of the total lipid present in the particle; and* *(d) a conjugated lipid that inhibits aggregation of particles comprising from 0.5 mol % to 2 mol % of the total lipid present in the particle.*
7	The nucleic acid-lipid particle of claim 1, wherein the cationic lipid comprises from 50 mol % to 60 mol % of the total lipid present in the particle.
12	The nucleic acid-lipid particle of claim 1, wherein the phospholipid comprises from 6 mol % to 12 mol % of the total lipid present in the particle.

B. '435 Patent

Claims 7, 8, and 16 of the '435 patent are currently asserted. All three claims depend from claim 1.

Claim No.	Claim Language
1	*A nucleic acid-lipid particle comprising:* *(a) a nucleic acid;* *(b) a cationic lipid comprising from 50 mol % to 85 mol % of the total lipid present in the particle;* *(c) a non-cationic lipid comprising from 13 mol % to 49.5 mol % of the total lipid present in the particle; and* *(d) a conjugated lipid that inhibits aggregation of particles comprising from 0.5 mol % to 2 mol % of the total lipid present in the particle.*
5	*The nucleic acid-lipid particle of claim 1, wherein the non-cationic lipid comprises a mixture of a phospholipid and cholesterol or a derivative thereof.*
7	The nucleic acid-lipid particle of claim 5, wherein the phospholipid comprises from 3 mol % to 15 mol % of the total lipid present in the particle.
8	The nucleic acid-lipid particle of claim 5, wherein the cholesterol or derivative thereof comprises from 30 mol % to 40 mol % of the total lipid present in the particle.
16	A method for the in vivo delivery of a nucleic acid, the method comprising: administering to a mammalian subject a nucleic acid-lipid particle of claim 1.

C. '378 Patent

Claims 2, 7, 13, 18, and 19 of the '378 patent are currently asserted. All five claims depend from claim 1.

Claim No.	Claim Language
1	*A nucleic acid-lipid particle consisting essentially of:* *(a) an RNA;* *(b) a cationic lipid having a protonatable tertiary amine;* *(c) a mixture of a phospholipid and cholesterol of from 30 mol % to 55 mol % of the total lipid present in the particle, wherein the phospholipid consists of from 3 mol % to 15 mol % of the total lipid present in the particle; and* *(d) a polyethyleneglycol (PEG)-lipid conjugate consisting of from 0.1 mol % to 2 mol % of the total lipid present in the particle.*
2	The nucleic acid-lipid particle of claim 1, wherein the cholesterol consists of from 25 mol % to 45 mol % of the total lipid present in the particle.
3	*The nucleic acid-lipid particle of claim 2, wherein the phospholipid is distearoylphosphatidylcholine (DSPC).*
4	*The nucleic acid-lipid particle of claim 3, wherein the PEG has an average molecular weight of about 2,000 daltons.*
5	*The nucleic acid-lipid particle of claim 4, wherein the PEG has a terminal methoxy group.*
6	*The nucleic acid-lipid particle of claim 5, wherein the PEG-lipid conjugate is a PEG-diacylglycerol (PEG-DAG) conjugate having the same saturated acyl groups.*
7	The nucleic acid-lipid particle of claim 6, wherein the cholesterol consists of from 35 mol % to 45 mol % of the total lipid present in the particle.
12	*The nucleic acid-lipid particle of claim 1, wherein the RNA is an mRNA.*
13	The nucleic acid-lipid particle of claim 12, wherein the cholesterol consists of from 25 mol % to 45 mol % of the total lipid present in the particle.
14	*The nucleic acid-lipid particle of claim 13, wherein the phospholipid is DSPC.*
15	*The nucleic acid-lipid particle of claim 14, wherein the PEG has an average molecular weight of about 2,000 daltons.*
16	*The nucleic acid-lipid particle of claim 15, wherein the PEG has a terminal methoxy group.*
17	*The nucleic acid-lipid particle of claim 16, wherein the PEG-lipid conjugate is a PEG-DAG conjugate having the same saturated acyl groups.*
18	The nucleic acid-lipid particle of claim 17, wherein the cholesterol consists of from 35 mol % to 45 mol % of the total lipid present in the particle.
19	A pharmaceutical composition comprising a nucleic acid-lipid particle of claim 17 and a pharmaceutically acceptable carrier.

D. '651 Patent

Claims 7, 9, 11, 13, and 14 of the '651 patent are currently asserted. All five claims depend from claim 1.

Claim No.	Claim Language
1	*A lipid vesicle formulation comprising:* *(a) a plurality of lipid vesicles, wherein each lipid vesicle comprises:* *a cationic lipid;* *an amphipathic lipid; and* *a polyethyleneglycol (PEG)-lipid; and* *(b) messenger RNA (mRNA), wherein at least 70% of the mRNA in the formulation is fully encapsulated in the lipid vesicles.*
4	*The lipid vesicle formulation of claim 1, wherein each lipid vesicle further comprises a sterol.*
6	*The lipid vesicle formulation of claim 4, wherein the sterol is cholesterol and the amphipathic lipid is a phospholipid.*
7	The lipid vesicle formulation of claim 6, wherein the phospholipid is selected from the group consisting of phosphatidylcholine, phosphatidylethanolamine, phosphatidylserine, phosphatidylinositol, phosphatidic acid, palmitoyloleoyl phosphatidylcholine, lysophosphatidylcholine, lysophosphatidylethanolamine, dipalmitoylphosphatidylcholine, dioleoylphosphatidylcholine, di stearoylphosphatidylcholine, and dilinoleoylphosphatidylcholine.
9	The lipid vesicle formulation of claim 1, wherein each lipid vesicle is a lipid-nucleic acid particle.
11	The lipid vesicle formulation of claim 1, wherein the cationic lipid only carries a positive charge at below physiological pH.
13	The lipid vesicle formulation of claim 1, wherein at least 80% of the mRNA in the formulation is fully encapsulated in the lipid vesicles.
14	The lipid vesicle formulation of claim 1, wherein about 90% of the mRNA in the formulation is fully encapsulated in the lipid vesicles.

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